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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,508	02/17/2004	K. C. Wong	5128.1 P	7874

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EXAMINER

SMITH, PAUL B

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/780,508	Applicant(s) WONG ET AL.	
	Examiner Paul B. Smith	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☒ Claim(s) 20-23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/17/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Applicant's claims to benefit of U.S. Provisional Patent Application Serial No. 60/464,260 filed April 21, 2003 are acknowledged.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 2/17/2004 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner considers the references cited therein.

Specification

3. Applicant is reminded of the proper content of an abstract of the disclosure.
4. A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use

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thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

5. The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

6. The abstract of the disclosure is objected to because it fails to provide a concise statement of the technical disclosure of the patent, which is new in the art. Correction is required. See MPEP § 608.01(b).

7. The disclosure is objected to because of the following informalities: As provided in 37 CFR 1.77(b), the specification fails to contain a section devoted a brief description of the views of the drawings. Appropriate correction is required.

Claim Objections

8. Claims 20, 21, 22 and 23 are objected to because of the following informalities: Medicine has been misspelled in the first line of each claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-16 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by McBeth *et al.* ('526).

11. McBeth *et al.* disclose a cannula comprising a proximal end (12), a distal end (14), a mechanical connection (47), a non-sharp tip (20), an elongate body (11), a hollow fluid passageway (30), a radial bulge (81), and at least one exit orifice (22). (See Figure 1, 8 and 9) The mechanical connection consists of a friction fit, such as a luer fitting. (See Column 4 Lines 55-60) A valve means (38) is disclosed to be a one-way flapper valve. (See Column 6 Lines 40-45)

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12. McBeth *et al.* discloses a method of aspirating medicine from a medicine vial comprising the steps of obtaining a vacuum source, connecting the vacuum source with the disclosed cannula, inserting distal end of cannula into medicine vial, aspirating medicine into a reservoir, and removing cannula from medicine vial. The vacuum source can comprise a piston cylinder assembly such as a syringe. The cylinder can also be said reservoir. (See Column 4 Line 55 to Column 5 Line 10)

13. Thus, it appears that McBeth *et al.* reasonably discloses every element of claims 1-16 and 19.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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16. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over McBeth *et al.* ('526) in view of Sellers *et al.* ('657).

17. McBeth *et al.* disclose a cannula comprising a proximal end (12), a distal end (14), a mechanical connection (47), a non-sharp tip (20), an elongate body (11), a hollow fluid passageway (30), a radial bulge (81), and at least one exit orifice (22). (See Figure 1, 8 and 9) The mechanical connection consists of a friction fit, such as a luer fitting. (See Column 4 Lines 55-60) A valve means (38) is disclosed to be a one-way flapper valve. (See Column 6 Lines 40-45)

18. McBeth *et al.* fails to disclose a radial bulge having a steeper curvature or slope on its proximal side than on its distal side.

19. Sellers *et al.* teaches a radial bulge (7) having a steeper curvature or slope on its proximal side than on its distal side. (See Figure 1)

20. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of McBeth *et al.* with the teachings of Sellers *et al.* to provide a radial bugle comprising a steeper proximal slope than distal slope.

21. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over McBeth *et al.* ('526) in view of Behnke *et al.* ('034).

22. McBeth *et al.* disclose a cannula comprising a proximal end (12), a distal end (14), a mechanical connection (47), a non-sharp tip (20), an elongate body (11), a hollow fluid passageway (30), a radial bulge (81), and at least one exit orifice (22). (See Figure 1, 8 and 9) The mechanical connection consists of a friction fit, such as a luer fitting. (See Column 4 Lines 55-60) A valve means (38) is disclosed to be a one-way flapper valve. (See Column 6 Lines 40-45)

23. McBeth *et al.* discloses a method of aspirating medicine from a medicine vial comprising the steps of; obtaining a vacuum source, connecting the vacuum source with the disclosed cannula, inserting distal end of cannula into medicine vial, aspirating medicine into a reservoir, and removing cannula from medicine vial. The vacuum source can comprise a piston cylinder assembly such as a syringe. The cylinder can also be said reservoir. (See Column 4 Line 55 to Column 5 Line 10)

24. McBeth *et al.* fails to specifically disclose a method for injecting medicine into an IV apparatus.

25. Behnke *et al.* teaches a method of injecting medicine into an IV using a blunt cannula comprising the steps of; introducing the cannula into the IV, and injecting medicine into the IV. (See Claim 26)

26. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of *McBeth et al.* with the teachings of *Behnke et al.* to provide a method for injecting medicine into an IV apparatus.

Conclusion

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Smith whose telephone number is 571-272-6022. The examiner can normally be reached on 8 am - 4 pm.

28. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

29. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul B Smith

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Examiner
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PBS
August 1, 2006

A handwritten signature in black ink, appearing to read "D. Lucchesi", with a stylized, flowing script.

NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3763